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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/661,156	09/11/2003	Aaron K. Sato	D0617.70012US00	6772

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EXAMINER	
DESAI, ANAND U	

ART UNIT	PAPER NUMBER
1656	

MAIL DATE	DELIVERY MODE
07/26/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/661,156	SATO ET AL.	
	Examiner	Art Unit	
	Anand U. Desai, Ph.D.	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 May 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-27,32,53,54,76,78,158,175,195,198 and 199* is/are pending in the application.

4a) Of the above claim(s) *1-9,11,12,27,32,53,54,76,158,175 and 195* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10,13-26,78,198 and 199* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *20070507*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This office action is in response to Amendment filed on May 7, 2007. Claims 1-9, 11, 12, 27, 32, 53, 54, 76, 158, 175, and 195 have been withdrawn previously. New claims 198 and 199 have been added. Claims 1-, 13-26, 78, 198, and 199 are currently pending and are under examination.

Election/Restrictions

2. SEQ ID NO: 310 is being considered to be an obvious variant of SEQ ID NO: 304-310, since Applicant state SEQ ID NO: 310 is a designated subset of the sequences for searching purposes (see Response to Restriction dated 9/18/2006, 2nd indented paragraph on page 2).

Information Disclosure Statement

3. The information disclosure statement (IDS) submitted on May 7, 2007 is being considered by the examiner.

Withdrawal of Rejections

4. The rejection of claim 10 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn based on the amendment to the claim.

5. The rejection of claims 10, 13, and 14 under 35 U.S.C. 102(b) as being anticipated by Bittle et al. (U.S. Patent 4,544,500) is withdrawn based on the amendment to the claims.

6. The rejection of claims 10, and 13-18 under 35 U.S.C. 102(b) as being anticipated by Soker et al. (Journal of Biological Chemistry 272(50): 31582-31588 (1997)) is withdrawn based on the amendment to the claims.

7. The rejection of claims 10, and 13-26 under 35 U.S.C. 102(e) as being anticipated by Wescott et al. (U.S. Patent 6,984,373 B2) is withdrawn based on the amendment to the claims.

Pending Objections and Rejections

Specification

8. The disclosure is objected to because of the following informalities:

9. The amendment filed May 7, 2007 for page 33, line 27 identifying SEQ ID NO: 377 is objected to because there is a typographical error. There is a period before the colon (SEQ ID NO.:377). Suggest, "SEQ ID NO: 377".

Appropriate correction is required.

Claim Objections

10. Claims 198 and 199 are objected to because of the following informalities:

There is a typographical error when identifying the amino acid sequences. The identifier has a period before the colon (SEQ ID NO.: 310). Suggest, e.g. "SEQ ID NO: 310".

Appropriate correction is required.

Double Patenting

11. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or

improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

12. Claims 78, 198 and 199 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim1, 11-20 of U.S. Patent No. 7,211,240 (Previously cited as US 2004/0018974 A1, SN 10/379,287 in office action mailed November 9, 2006). Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the copending application are drawn to a compound comprising a polypeptide sequence that is encompassed by claims 78, 198, and 199, and can bind to the same tyrosine kinase receptor, KDR, and the ligand-receptor complex, KDR/VEGF. SEQ ID NO: 18 of the issued U.S. Patent has 100% identity with SEQ ID NO: 308 of the instant application. The SEQ ID NO:'s are considered to be an obvious variant of each other, since Applicant state SEQ ID NO: 310 is a designated subset of the sequences for searching purposes (see Response to Restriction dated 9/18/2006, 2nd indented paragraph on page 2).

Response to Remarks

13. Applicants' state the rejection is a provisional one and will therefore defer substantive rebuttal until one or more claims are found allowable.

Claim Rejections - 35 USC § 112, First Paragraph, Written Description

14. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

15. Claims 10, 13-26, and 78 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The rejection was explained in the office action mailed November 9, 2006.

Response to Remarks

16. Applicants' state that various polypeptides are demonstrated that are capable of binding to KDR or VEGF/KDR complex. Applicants' state they have adequately disclosed methods for preparing libraries of polypeptides and provided details of how to screen them for their ability to bind KDR or VEGF/KDR using phage display technology. Applicants' state they have provided sequence information of specific polypeptides within each disclosed library. The phage display library was created to provide a phage population displaying a vast number of different but structurally related amino acid sequences. The amino acid variations are designed to alter the

binding properties of the binding peptide or domain without significantly altering its structure. The structure function relationship is clearly disclosed in that changes to the polypeptide sequences are contemplated that do not significantly affect the structure of the polypeptide buy may alter the binding affinity of that polypeptide. Applicants' state modifications, such as biotinylation and the inclusion of a JJ spacer have demonstrated that such modified polypeptides retain the ability to bind KDR. Applicants' state modifications to amino acid sequences are methods known and used widely by those of ordinary skill in the art. The precise structure of each amino acid residue is known and those of ordinary skill in the art are adequately experienced to make modifications to a peptide sequence that does not significantly alter the polypeptide structure and retains or improves the function of that polypeptide.

Applicant's arguments filed May 7, 2007 have been fully considered but they are not persuasive. MPEP § 2163 does state that for a generic claim the genus can be adequately described if the disclosure presents a sufficient number of representative species that encompass the genus. If the genus has a substantial variance, the disclosure must describe a sufficient variety of species to reflect the variation within that genus. In the instant case, the claims are drawn to an isolated polypeptide having the ability to bind to kinase insert domain-containing receptor (KDR) or vascular endothelial growth factor(VEGF)/KDR complex comprising an amino acid sequence with a consensus sequence identified as Z_1-X_1-X_2-X_3-X_4-X_5-Z_2 that further comprises N-terminal and/or C-terminal flanking peptides of one or more amino acids. The isolated polypeptide can also comprise modifications selected from a group consisting of an amino acid substitution, an amid bond substitution, a D-amino acid substitution, a glycosylated amino acid, a disulfide bond, a disulfide mimetic substitution, an amino acid translocation, a

retroinverso peptide, a peptoid, a retro-inverso peptoid, and a synthetic peptide. The isolated peptide is also conjugated to one or more detectable labels, optionally further comprising a linker or spacer between the polypeptide and the detectable label. The detectable label can further comprise a chelator. Claim 78 is drawn to a multimeric polypeptide construct having the ability to bind to KDR or VEGF/KDR complex comprising an amino acid sequence with a consensus sequence identified as Z_1-X_1-X_2-X_3-X_4-X_5-Z_2 that can further comprises N-terminal and/or C-terminal flanking peptides of one or more amino acids.

The claims encompass an isolated polypeptide, wherein the variables Z_1 and Z_2 are any polypeptides of at least one amino acid. Claim are broadly generic to all possible polypeptides, which also include any modifications, such as any amino acid substitution as encompassed by the claims. The possible variations are enormous to any class of isolated polypeptide. Since the MPEP states that if a biomolecule is described only by a functional characteristic, without any disclosed correlation between function and structure, it is "not sufficient characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence." MPEP § 2163. Here, though the claims may recite some functional characteristics, the claims lack written description because there is no disclosure of a correlation between function and structure of the modified polypeptide beyond those disclosed in the examples in the specification. Moreover, the specification lacks sufficient variety of species to reflect this variance in the genus. The specification does not disclose a representative number of multiple species of Z_1 or Z_2 polypeptides that can be linked to the polypeptide, which will not alter the functional ability of binding KDR or VEGF/KDR complex.

Conclusion

17. No claims are allowed.

18. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anand U. Desai, Ph.D. whose telephone number is (571) 272-0947. The examiner can normally be reached on Monday - Friday 9:00 a.m. - 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Kathleen Kerr Bragdon can be reached on (517) 272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

July 21, 2007

/Anand Desai/
Patent Examiner
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July 22, 2007